Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 117-179 are pending in the application, with 117, 122, 134, 141, 148, 155, 162, and 174 being the independent claims. Claims 23-116 are sought to be cancelled without prejudice to or disclaimer of the subject matter therein. Support for claims 117-179 can be found in the claims as filed and throughout the specification. These new claims have been added to advance prosecution and to make explicit that which was implicit in earlier pending claims. *See Interactive Pictures Corp. v. Infinite Pictures Inc.*, 61 U.S.P.Q.2d 1152, 1157 (Fed. Cir. 2001). These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Interview With the Examiner

Applicants thank Examiners Nirmal Basi and Yvonne Eyler for the courtesy extended in the personal interview held on April 23, 2002 with Eric Steffe and Elizabeth Haanes. The claims presented herein and the following remarks reflect the issues that were discussed in that interview.

Rejections under 35 U.S.C. § 112, Second Paragraph

In Paper No. 8, the Examiner rejected claims 35, 47, 60, 73, 82, 83, 93, 94-97 and 99 under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite.

The Examiner stated that claim 93 "is indefinite because it is not clear which amino acids comprise the transmembrane domain of SEQ ID NO:2 so as to allow the metes and bounds of the claims to be determined." Paper No. 8, page 4. Solely to advance prosecution, and not in acquiescence to the Examiner's rejection, Applicants have canceled claim 93, thereby rendering this rejection moot. Applicants respectfully request that the Examiner withdraw the rejection.

The Examiner states that claims 35, 47, 60, and 73 are indefinite "because it is unclear what 'activity' the G-protein coupled receptor has" and that "the 'activity' of the G-protein coupled receptor has not been disclosed in the claims nor the specification." Paper No. 8, page 4. Solely to advance prosecution, and not in acquiescence to the Examiner's rejection, Applicants have canceled claims 35, 47, 60, and 73 thereby rendering this rejection moot. Accordingly, the Examiner is respectfully requested to withdraw the rejection.

The Examiner states that claim 82 and dependent claim 83 are indefinite "because it is unclear what is the mature polypeptide." Paper No. 8, page 4. Solely to advance prosecution, and not in acquiescence to the Examiner's rejection, Applicants have canceled claims 82 and 83, thereby rendering this rejection moot. Accordingly, Applicants respectfully request that the Examiner withdraw the rejection.

Claim Rejections under 35 U.S.C. § 101

Claims 23-29, 31, 33-39, 41, 43-51, 53, 55-64, 66, 68-77, 79, 81-89, 91, 93-97 and 99 were rejected under 35 U.S.C. § 101 for allegedly not being supported by either a specific, substantial utility or a well established utility. Claims 23-29, 31, 33-39, 41, 43-51, 53, 55-64, 66, 68-77, 79, 81-89, 91, 93-97 and 99 have been canceled. As far as this rejection applies to new claims 117-179, Applicants respectfully assert that the remarks and arguments regarding utility made in the Amendment and Reply dated January 10, 2002 are fully applicable, and are incorporated by reference herein.

During a personal interview on April 23, 2002, the utility rejection was discussed. The Examiners in attendance acknowledged the assertion in the specification of at least one specific and substantial utility. In fact, as discussed in the interview, several utilities are asserted, primarily relating to diagnosis and treatment of vascular, coronary, and nervous tissue diseases, as well as cancers. *See, e.g.*, the specification at page 8, lines 18-20. Therefore, the remaining issue appears to be whether Applicants' asserted utility is "credible."

According to the USPTO guidelines, if a specific and substantial utility is asserted, the Examiner must "establish that it is more likely than not that a person skilled in the art would not consider credible any specific and substantial utility asserted by the applicant for the claimed invention." *Utility Examination Guidelines*, 66 Fed. Reg. 1092 at 1098 (Jan. 5, 2001).

The Guidelines further note that:

> Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record (e.g., test data, affidavits or declarations from experts in the art, patents or printed publications) that is probative of the applicant's assertions. An applicant need only

> provide *one credible assertion* of specific and substantial utility for each claimed invention to satisfy the utility requirement.

Id. (emphasis added). Additional statements of utility, even if not "credible," do not render the claimed invention lacking in utility. *See, e.g., Raytheon v. Roper*, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 835 (1984) ("When a properly claimed invention meets at least one stated objective, utility under 35 U.S.C. § 101 is clearly shown.").

In contrast, the Examiner appears to require that Applicants demonstrate a reasonable "linkage" or nexus between the claimed EBI-2-encoding polynucleotides, and *each* specific and substantial utility disclosed in the specification, or at least the generic "category" of utilities disclosed. As Applicants understand the Examiner's position, the skilled artisan should be able to reasonably confirm a specific and substantial utility without further research.

While not agreeing with the Examiner's position, Applicants nonetheless point out that a reasonable "linkage" or nexus between the claimed EBI-2-encoding polynucleotides, and the general category of specific and substantial utilities disclosed in the specification does, indeed exist. Applicants identified the claimed polynucleotides in cDNA libraries from umbilical vein endothelial cells (vascular tissue), neutrophil leukocyte cells (myeloid tissue, derived from the same progenitor cells as lymphoid tissue), and corpus callosum cells (brain or nervous tissue). *See* the specification at page 7, lines 9-10. Given the expression of EBI-2 mRNA in these tissues, one of ordinary skill in the art would logically investigate functions and utilities related to vascular, cardiac, or nervous system disorders. In addition, the G protein-coupled receptor encoded by SEQ ID NO:1 is closely related to certain G protein-coupled receptors known to be induced upon Epstein-Barr virus (EBV) infection. *See* the

specification at page 1, lines 15-18. These related EBI receptors are primarily expressed in lymphoid tissues, and are related to thrombin receptors. *See* Birkenbach *et al. J. Virol. 67*:2209-2220 (1993)(Exhibit A). EBV and related gamma-herpesvirus infections are often associated with vascular and cardiac diseases (*see, e.g.*, Kikuta *et al., J. Pediatr. 123*:90-92 (1993)(Exhibit B), and Tyson *et al., South. Med. J. 82*:1184-1187 (1989)(Exhibit C)) and cancers such as Hodgkin's disease and Burkitt's lymphoma (*see, e.g.*, Grasser, *et al., Blood 84*:3972-3978 (1994)(Exhibit D)) and neurological disorders (*see, e.g.*, Connelly and DeWitt *Pediatr. Neurol. 10*:181-4 (1994)(Exhibit E)). Based on the relationship to EBI receptors, one of ordinary skill in the art would again logically investigate functions and utilities related to vascular, cardiac, or nervous system disorders. Thus the claimed polynucleotides certainly provide identifiable benefit which is easily linked to general categories of diseases and disorders disclosed in the specification. This linkage was later borne out by Hollopeter, G. *et al., Nature 409(6817)*:202-7 (2001), which was submitted with the Amendment and Reply dated January 10, 2002. Hollopeter *et al.* demonstrates that the EBI-2 receptor of the present invention is primarily expressed in platelets (myeloid lineage) and brain (see Fig. 4), and that differential EBI-2 expression may indicate a perturbation in platelet aggregation, which can lead to myocardial infarction. Thus, this publication confirms a reasonable nexus between EBI-2 as disclosed in the present application, and the treatment and/or detection of heart disease.

In view of the facts and relationships set out above, Applicants submit that a skilled artisan would not reasonably doubt that the claimed polynucleotides can be useful in making EBI-2 proteins, generating antibodies, or diagnosing and/or treating heart diseases, cancer, or neurological diseases. As such, Applicants have met their burden of showing that the

presently claimed invention possesses a credible, specific and substantial utility that constitutes a patentable utility under 35 U.S.C. § 101, and the burden now shifts to the Examiner to either refute the evidence presented by Applicants or to withdraw the rejection. Indeed, the USPTO has established that

> Only where *the totality of the record* continues to show that the asserted utility is not specific, substantial, and credible should a rejection based on lack of utility be maintained.

Utility Examination Guidelines, 66 Fed. Reg. 1092 at 1099 (Jan. 5, 2001)(emphasis added).

Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 101 be reconsidered and withdrawn.

Claim Rejections under 35 U.S.C. § 112, First Paragraph

Claims 23-29, 31, 33-39, 41, 43-51, 53, 55-64, 66, 68-77, 79, 81-89, 91, 93-97 and 99 were rejected under 35 U.S.C. § 112, first paragraph for alleged lack of enablement. Paper No. 8., page 13. Claims 23-29, 31, 33-39, 41, 43-51, 53, 55-64, 66, 68-77, 79, 81-89, 91, 93-97 and 99 have been canceled. With respect to new claims 117-179, Applicants reiterate the remarks made previously. For the reasons discussed in the Amendment and Reply dated January 10, 2002, as well as the remarks above, Applicants respectfully assert that the claimed invention is supported by a specific, substantial and credible asserted utility. The Examiner "should not impose a 35 U.S.C. 112, first paragraph, rejection grounded on a 'lack of utility' basis unless a 35 U.S.C. 101 rejection is proper." M.P.E.P. § 2107 (IV) at 2100-28. Therefore, because the claimed invention complies with the utility requirement of 35 U.S.C. § 101, the rejections under 35 U.S.C. § 112, first paragraph, based on the alleged lack of utility of the claimed invention, should be withdrawn.

Claims 23-29, 31, 33-39, 41, 43-51, 53, 55-64, 66, 68-77, 79, 81-89, 91, 93-97 and 99 were rejected under 35 U.S.C. § 112, first paragraph for alleged lack of written description. According to the Examiner:

> [t]he instant disclosure of a polynucleotide of SEQ ID NO:1 encoding the polypeptide of SEQ ID NO:2 (EBI-2) does not adequately describe the scope of the use of the claimed genus of polynucleotides encoding polypeptides, which encompass a substantial variety of subgenera including full-length proteins, mature proteins, epitope region bearing polypeptides, chimeric proteins, fusion proteins, and variants . . . .

Paper No. 8 at pages 17-18.

As set forth in the Amendment and Reply dated January 10, 2002, Applicants respectfully disagree with the Examiner. However, solely to advance prosecution, and not in acquiescence to the Examiner's rejection, Applicants have canceled claims 23-29, 31, 33-39, 41, 43-51, 53, 55-64, 66, 68-77, 79, 81-89, 91, 93-97 and 99 and added new claims 117-179, in which the Examiner's concerns about the "substantial variety of subgenera" are obviated. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection.

Rejections Under 35 U.S.C. § 112, First Paragraph - Deposit Rules

Claims 23-29, 31, 33-39, 41, 43-51, 53, 55-64, 66, 68-77, 79, 81-83, 84-89, 91, 94-97 and 99 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly being nonenabled for reciting deposited biological material. The Examiner required that the specification be amended to recite the address of the ATCC, and required that particular averments be made concerning the deposit.

Applicants previously amended the specification accordingly. A "Statement

Concerning the Deposited cDNA Clone" which contains the necessary averments was submitted on April 3, 2002. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

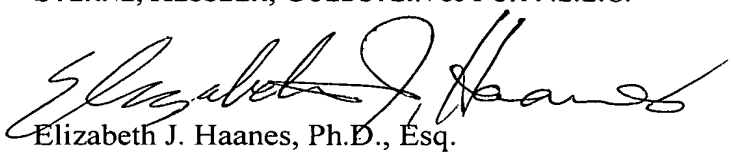
Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicant(s) therefore respectfully request(s) that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicant(s) believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Elizabeth J. Haanes, Ph.D., Esq.
Attorney for Applicants
Registration No. 42,613

Date: May 31, 2002

1100 New York Avenue, N.W.
Suite 600
Washington, D.C. 20005-3934
(202) 371-2600

Version with markings to show changes made

Claims 23-116 have been canceled.

Claims 117-179 are new.